Proposed Changes to ISO/IEC 17025

Warren Merkel

Standards Services

Standards Coordination Office

Overview

- Revision process so far
- Significant proposed changes
- Next steps

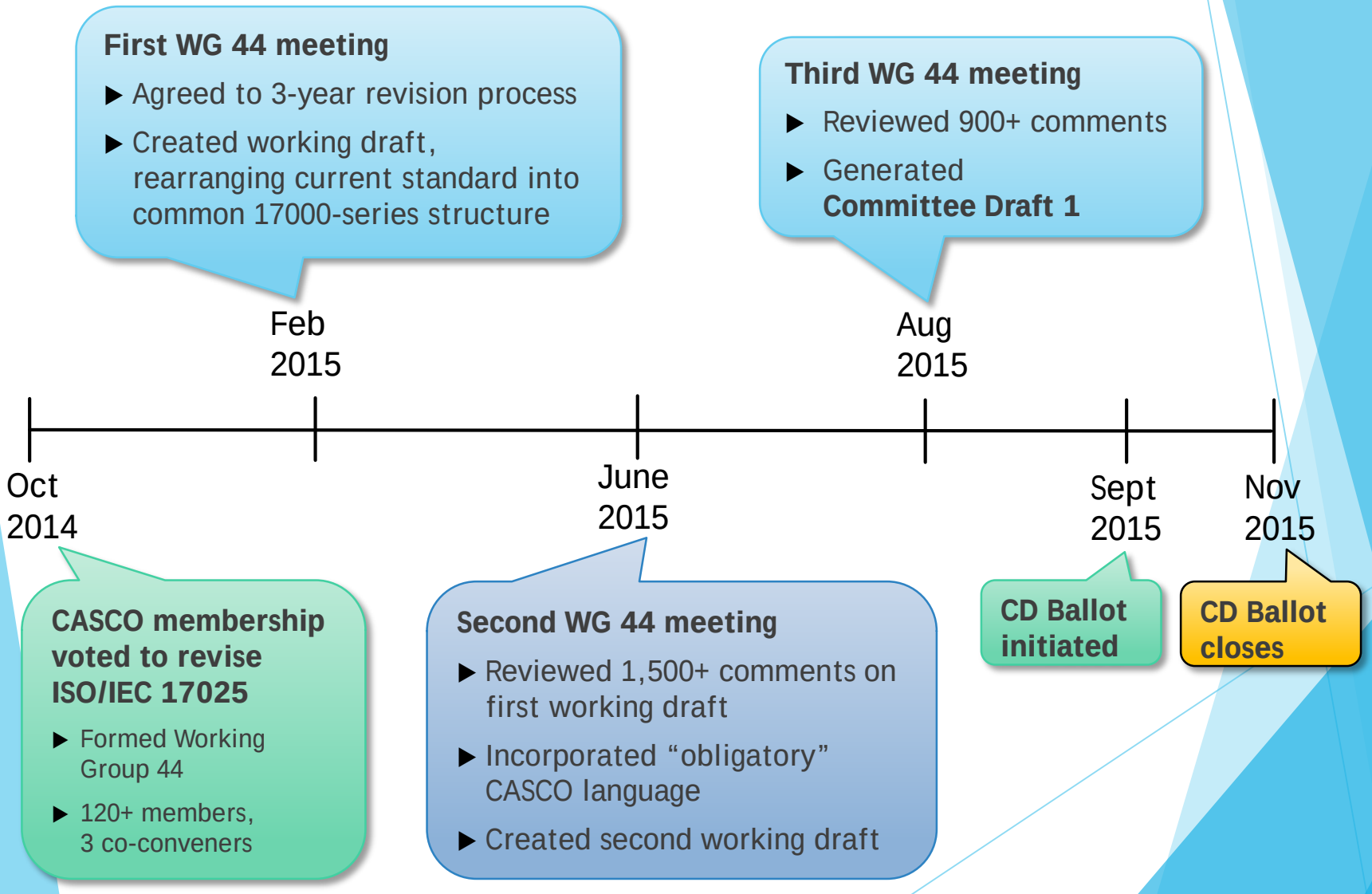
More acronyms…

WG 44: ISO CASCO Working Group on revision of ISO/IEC 17025

CD: Committee Draft

FDIS: Final Draft International Standard

Revision process so far…



CD1 ISO/IEC 17025

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

- 4.1 Impartiality
- 4.2 Confidentiality

5 Structural requirements

6 Resource requirements

- 6.1 General
- 6.2 Personnel
- 6.3 Accommodation and environmental conditions
- 6.4 Externally provided products and services
- 6.5 Equipment
- 6.6 Metrological traceability

"Obligatory" language from CASCO

7 Process requirements

- 7.1 Review of requests, tenders and contracts
- 7.2 Sampling
- 7.3 Handling of test or calibration items
- 7.4 Evaluation of uncertainty of measurement
- 7.5 Reporting of results
- 7.6 Assuring the quality of results
- 7.7 Selection, verification and validation of methods
- 7.8 Management of nonconforming work
- 7.9 Technical records
- 7.10 Control of data – information management
- 7.11 Complaints

8 Management requirements

Annex A Metrological traceability

Annex B Management system

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Annex A Metrological traceability

Annex B Management system

6.6 Metrological traceability

- **Updated, streamlined language**
  - Eliminated separate language for testing and calibration laboratories
  - Annex A (informative) added
  - Does not include all the specific requirements imposed by the International Laboratory Accreditation Cooperation (ILAC)

7.1 Review of requests, tenders and contracts

- **More detail regarding statements of compliance**
- Added requirement:

  "…when the customer requests a verification of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance):

  - the specification is clearly defined in the procedure selected;
  - the decision rule for conformity, its level of risk and statistical assumptions is documented in the test method/procedure or is documented by the laboratory and communicated to the customer;
  - the decision rule is agreed to by the customer."
- More language likely to be added in clauses on Uncertainty of Measurement and Reporting of Results

7.4 Evaluation of uncertainty of measurement

- **Clearer requirement for calibration**
  - "A laboratory performing calibrations shall have and shall apply procedures to evaluate the uncertainty of measurement for all calibrations."
- **Requirements for testing laboratories still loose…**
  - Previous note related to use of well-recognized test methods now in body of standard
  - New note:

    "For a particular test method used in testing laboratories where the relevant measurement uncertainty of test results obtained with the method is known, there is no need to estimate uncertainty of measurement for each test result, if the identified critical influencing factors are under control and remain unchanged."

7.9 Technical records

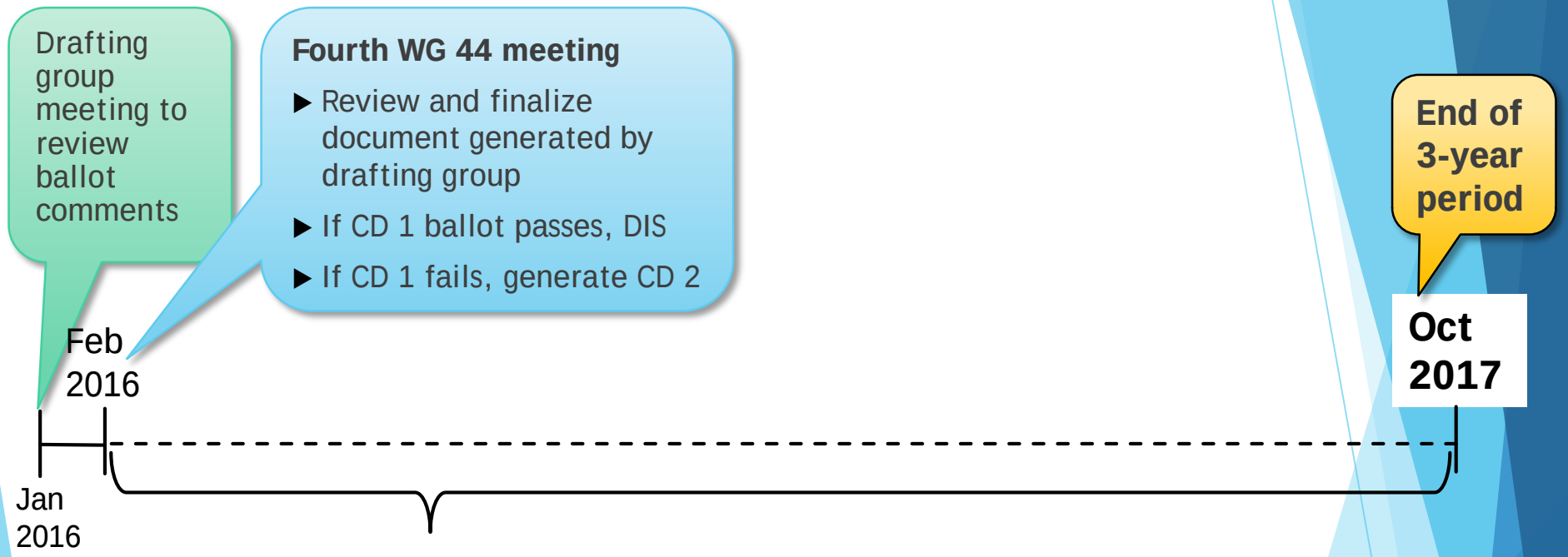
7.10 Control of data – information management

- **Updated language**
  - Written primarily around electronic systems, without precluding paper-based systems
  - Focused on traceability of results, records, and data to original observations, identifying any changes made along the way
  - Did not adopt ISO 9001:2015 approach of “documented information”

8 Management requirements

- **Two options for management system structure**
- Option A: states minimum requirements
  - Management system documentation
  - Control of management system
  - Control of records
  - Improvement
  - Corrective action
  - Internal audits
  - Management review
- Option B: Meet ISO 9001 and rest of ISO/IEC 17025
- Informative Annex added to further explain

Next steps…



~20 months left…

- CD 2: 2 months (only required if CD 1 ballot fails)
- DIS Ballot: 5 months (required)
- FDIS Ballot: 2 months (required)
- Earliest release: End of 2016
- Likely release: 3rd quarter 2017

Warren Merkel
warren.merkel@nist.gov
x 6081